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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,198	07/25/2003	Daniel Boyd Brown	Z70606-2 US	2704

22466 7590 01/21/2005

ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/627,198

Applicant(s)

BROWN, DANIEL BOYD

Examiner

Raymond J Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☒ Claim(s) 7,11,36 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/088,804.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**CLAIMS 1-38 ARE PRESENTED FOR EXAMINATION**

Applicant's Preliminary Amendments filed July 25, 2003, July 6, 2004 and November 29, 2004 and Information Disclosure Statement filed July 25, 2004 have been received and entered into the application.

Accordingly, the specification at page 1 and claims 5, 6, 9, 16 and 17 have been amended and claims 18-38 have been added. Also, as reflected by the attached, completed copy of form PTO-1449 (1 page), the cited references have been considered.

***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "QUETIAPINE GRANULES".

***Claim Objections***

Claims 7 and 11 are objected to because of the following informalities:

In claim 7, line 4, "0.60 glcc" should read ---0.60 g/cc---; and in claim 11, line 3, "ehtyl" should read ---ethyl---.

Claims 36 and 37 are objected to because they fail to further limit the subject matter of claim 12. In particular, claim 12 fails to provide antecedent basis for the expression "the disease of the central nervous system" as recited in claims 36 and 37.

Appropriate correction is required.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and

Art Unit: 1614

useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-38 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-38 of Brown (prior U.S. Patent No. 6,599,897, cited by the Examiner). This is a statutory double patenting rejection because in both the present claims and the claims of the patent, the same invention is defined.

***Straub et al.***

Straub et al. (U.S. Patent Application Publication No. 2002/0142050) is cited on the attached form PTO-892 to show the general state of the art. For the reasons that follow, the Examiner believes that Straub et al. do not teach or suggest the presently claimed subject matter:

Straub et al. teach the following pharmaceutical composition at claim 1 (page 13, col. 1):

1. A pharmaceutical composition comprising a porous matrix formed of a hydrophilic or hydrophobic excipient and microparticles of a drug,

wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and

wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .

Straub et al. further teach that "a drug" may be quetiapine fumarate, i.e., the fumarate salt of the presently claimed "11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine (see the present specification at page 1, first and second paragraphs).

Applicant's pharmaceutical composition is represented by present claim 1 which reads:

Art Unit: 1614

**Claim 1 (original) A granule formulation comprising 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and a freely or very water-soluble binder, wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns.**

Straub et al. recite that the surface area of the drug microparticles is greater than 0.5 m<sup>2</sup>/g (claim 1) while the surface area of Applicant's composition has not been stated in either the claims or the specification. Nevertheless, Applicant's composition does inherently have a surface area. It is not believed, however, that the surface area of the presently claimed composition is taught or suggested by the composition of Straub et al. In particular, the surface area of a powdered composition is a function of the size of the particles which comprise the composition. The particle size of the particles contained in the composition of Straub et al. is stated to be between about 1 and 5  $\mu$ m (claim 1) while the particle size of 80% of the particles in the presently claimed composition is in the range of from 75 to 850 microns, i.e.,  $\mu$ m. A larger particle size would mean less particles per given quantity of area. The particle sizes as presently claimed are approximately from 75 to 170 times larger than those of Straub et al. and it would therefore follow that the surface area of the presently claimed composition would be correspondingly smaller than that of Straub et al.

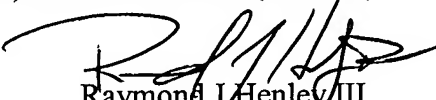
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

Art Unit: 1614

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J. Henley III  
Primary Examiner  
Art Unit 1614

January 18, 2005